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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,257	11/13/2001	Barry Douglas Moore	31749/241015	8521

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,257	Applicant(s) MOORE ET AL.	
	Examiner Susan Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: . |

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DETAILED ACTION

Receipt is acknowledged of applicant's Declaration filed 05/29/02, and Information Disclosure Statement filed 02/19/02.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 10, 24, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 10, 24, and 25 are rejected in the use of the phrase "for example" or "such as". The phrase renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, 10-12, 22, 24, 25, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Randen et al. J. Pharm. Pharmacol (XP-000973058).

Randen teaches method of coprecipitation of enzymes with water-soluble starch. The method comprises preparing an aqueous solution of enzymes (krill protease) and water-soluble starch; mixing the aqueous solution with organic solvent, such as ethanol, acetone, or isopropanol to cause rapid precipitation; collecting the precipitate; drying the precipitate; and milling the dried precipitate to obtain micronized particle (pages 763-766).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 20-25, 27, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randen et al.

Randen is relied upon for the reason stated above. The reference is silent as to the teaching of particle having size of less than 50 μm . However, Randen teaches the irregular shape particles or precipitate is further micronized by milling or grinding to obtain a more uniform particle size distribution (pages 763-764). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to, by routine experimentation obtain particle having size of less than 50 μm , because the reference teaches micronized, milling, or grinding the particle to obtain a desirable microparticle size.

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Claims 22 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novo WO 97/34919.

Novo teaches method for purification of a protein from protein containing solution. The method comprises crystallizing protein from protein solution with water-miscible organic solvent, and isolating after crystallization (pages 17-18). It is the position of the examiner that it would have been obvious for one of ordinary skill in this art to modify Novo's method with the expectation of at least similar result, because Novo teaches similar method using same materials to obtain useful crystalline protein product.

Claims 1-5, 13-21, 23, and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawkins et al. US 5,198,353, and Langley et al. EP 0 356 239.

Hawkins teaches method for preparing stabilized enzyme dispersion comprising coprecipitating enzyme and polymer in aqueous solution, mixing the enzyme and polymer solution with organic solvent, obtaining the precipitant (columns 3-6, and examples). The polymer being used can be selected from polymer having molecular weight of from 1,000 Da (column 2).

Hawkins is silent as to the teaching of particle size of less than 50 μm .

Langley teaches process for preparing stable dispersion of small particles comprising dispersion of enzyme and polymer in liquid solution and precipitated with a solvent phase to obtain particle having size of below 20 μm (columns 2-7, and claims). Thus, it would have been obvious for one of ordinary skill in the art to modify Hawkins's

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process with the teachings of Langley to obtain particle having size of less than 20 μm , because the references teach the advantageous results of enzyme dispersion process.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Groman et al., and Bustos et al. are cited as being of interest for the teachings of stable dispersion of small particles.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500